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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(s): CUBERES ALTISEN et al.

SERIAL NO.: 10/804,558 ART UNIT:

FILING DATE: 3/19/04 EXAMINER:

TITLE: SUBSTITUTED AZETIDINE COMPOUNDS, THEIR  
PREPARATION AND USE AS MEDICAMENTS

ATTORNEY

DOCKET NO.: 785-011731-US (PAR)

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
(37 C.F.R. §1.97(b)(3))

Sir:

This information disclosure statement is being filed before the mailing of a first Office Action on the merits.

The following information is being disclosed to the Patent and Trademark Office as information that may be material to the examination of the above-identified patent application. Applicants' Attorney is aware of the following references:

US 5,073,646

DE 299 21 689 U1

"Health Aspects of Cannabis", Leo E. Hollister

"Chemistry and pharmacology of cannabis", Renu Seth et al.

"Potential Role of Cannabinoids for Therapy of Neurological Disorders", Consroe and Sandyk

"Novel Syntheses of 1,3,3-Trinitroazetidine", Alan R. Katritzky,  
et al.

"Acylative Dealkylation of *N*-tert-Butyl-3-substituted Azetidines:  
Facile Access to [1.1.0] Azabicyclobutane, 3-Hydroxyazetidinium  
Hydrochloride, and 3-Azetidinones", Paritosh R. Dave

"Synthesis of Novel Four-Membered Ring Amino Acids as Modulators  
of the *N*-Methyl-D-Aspartate (NMDA) Receptor Complex", Alan P.  
Kozikowski, et al.

"Synthesis of 1,3,3-Trinitroazetidine", Theodore Axenron, et al.

"The selective formation of unsaturated alcohols by hydrogenation  
of  $\alpha,\beta$ -unsaturated aldehydes in supercritical carbon dioxide using  
unpromoted Pt/Al<sub>2</sub>O<sub>3</sub> catalyst", Bhalchandra M. Bhanage, et al.

"Studies on  $\beta$ -Methyl-1-and 3-Phenyl Allyl Chlorides", M.Y.  
Shandala, et al.

"Selective Reduction of Carbonyl Compounds by  
Polymethylhydrosiloxane in the Presence of Metal Hydride  
Catalysts", Hubert Mimoun et al.

"Catalytic Asymmetric Cyclopropanation of Allylic Alcohols with  
Titanium-TADDOLate: Scope of the Cyclopropanation Reaction",  
Andre B. Charette, et al.

"Thionyl Chloride-Benzotriazole in Methylene Chloride: A  
Convenient Solution for Conversion of Alcohols and Carboxylic  
Acids Expeditiously into Alkyl Chlorides and Acid Chlorides by  
Simple Titration", Sachin S. Chaudhari, et al.

"Activation de la liaison silicium-halogene par les halogenures  
de bismuth (III). Halogenation des alcohols: perspectives et  
mecanisme [1]", Mireille Labrouillere, et al.

"Syntheses of Two Cytotoxic Sinapyl Alcohol Derivatives and Isolation of Four New Related Compounds from *Ligularia nelumbifolia*", Yu Zhao, et al.

"Towards an Understanding of Cram/anti-Cram selectivity on Addition of Crotylboronates to  $\alpha$ -Methylbutyraldehyde", Reinhard W. Hoffmann

"Stereospecific Synthesis of 2,3,6-Trisubstituted Piperidines: An Efficient Total Synthesis of ( $\pm$ )-Pumiliotoxin C<sup>1</sup>", Norman A. LeBel, et al.

"Triphenylphosphine/Dichloroselenurane: A New Reagent for a Selective Conversion of Alcohols into Alkyl Chlorides", Jozef Drabowicz, et al.

"Formation of indole nucleus via intramolecular cyclization of aminophenylpropenyltriphenylphosphonium salts with one-carbon degradation", Shin'ichi Taira et al.

"Benzophenone Derivatives and Related Compounds as Potent Histamine H<sub>3</sub>-Receptor Antagonists and Potential PET/SPECT Ligands<sup>1)</sup>", Astrid Sasse, et al.

"Stereoselective Syntheses of Spicy Components in Peppers", Akihiro Ohta, et al.

"Negative Inotropic and Calcium Antagonistic Activity of Alkyl and Arylalkyl Phosphonates", Cristina Bellucci, et al.

"Synthesis of 6-(3-Aryl-2-propenyl)-2,3-dihydro-5-hydroxybenzofuran Derivatives by Cross Coupling Reactions", Ramon J. Alabaster, et al.

"Antioxidant-Based Inhibitors of Leukotriene Biosynthesis. The Discovery of 6-[1-[2-(Hydroxymethyl)phenyl]-1-propen-3-yl]-2,3-

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Milton L. Hammond, et al.

"Configurational Analysis of 1-Alkyl-2-Methylazetidin-3-ols",  
Robert H. Higgins, et al.

"New Synthesis of 2-Azetines and 1-Azabutadienes and the Use of  
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"Cyclization of 1-Alkylamino-3-halo-2-alkanols to 1-Alkyl-3-  
azetidinols", V.R. Gaertner

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"A Short, Efficient Synthesis of Substituted Uracil: An Indane  
Carbocyclic Nucleoside", Franco Fernandez, et al.

"Benzhydryl and Fluorenyl Lactamimides with Hypoglycemic,  
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"Synthesis of Substituted Benzhydrylamines", Yves Dejaegher, et al.

"7-Azetidinylquinolones as Antibacterial Agents. Synthesis and  
Structure-Activity Relationships", Jordi Frigola et al.

"7-Azetidinylquinolones as Antibacterial Agents. 1. Synthesis  
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with an Azetidine Moiety", Jordi Frigola, et al.

"7-Azetidinylquinolones as Antibacterial Agents. 3. Synthesis,  
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"Progress toward the Total Synthesis of Bafilomycin A<sub>1</sub>: Stereoselective Synthesis of the C15-C25 Subunit by Additions of Nonracemic Allenylzinc Reagents to Aldehydes", James A. Marshall, et al.

"Amberlyst-15 (H<sup>+</sup>) -NaBH<sub>4</sub>-LiCl: An Effective Reduct for Oximes and Hydrazones", Bipul Baruah et al.

"The Synthesis of Azetidine-3-carboxylic Acid", Arthur G. Anderson, et al.

"The Azetidines, Recent Synthetic Developments", Norman H. Cromwell, et al.

"Synthese de l'amino-3 azetidine", Dino Nisato, et al.

"A Short Enantioselective Synthesis of N-Boc- $\alpha$ -Amino Acids from Epoxy Alcohols", Marta Poch, et al.

"A Versatile Enantiospecific Approach to 3-Azetidinols and Aziridines", Marta Poch, et al.

"Synthesis of 1-Alkyl-3-Hydroxy-2-Phenylazetidines", Takashi Toda, et al.

"Ring Opening of Azetidinols by Phenols: Regiochemistry and Stereochemistry", Robert H. Higgins, et al.

"Synthetic Applications of 1-Aminoalkyl Chloromethyl Ketones. Synthesis of Enantiopure 3-Azetidinols and Aminoalkyl Epoxides", Jose Barluenga, et al.

"A human whole blood assay for clinical evaluation of biochemical efficacy of cyclooxygenase inhibitors", Brideau et al.

"Reactivos Bioquimicos y Organicos para investigation en biociencias" Sigma

"Basic Section, A new and sensitive method for measuring thermal nociception in cutaneous hyperalgesia", K. Hargreaves, et al.

"Carrage Edema in Hind Paw of the Rat as an Assay for Antiinflamatory Drugs", Charles A. Winter, et al.

"Selective Inhibition of Cyclooxygenase (COX)-2 Reverses Inflammation and Expression of COX-2 and Interleukin 6 in Rat Adjuvant Arthritis", Gary D. Anderson, et al.

"Effect of nimesulide on cyclo-oxygenase activity in rat gastric mucosa and inflammatory exudate", O. Tofanetti, et al.

"New Cyclooxygenase-2/5-Lipoxygenase Inhibitors. 1. 7-tert-Butyl-2,3-dihydro-3,3-dimethylbenzofuran Derivatives as Gastrointestinal Safe Antiinflamatory and Analgesic Agents: Discovery and Variation of the 5-Keto Substituent", John M. Janusz, et al.

4 pages of Product Information by product number from product catalog ([www.caymanchem.com](http://www.caymanchem.com))

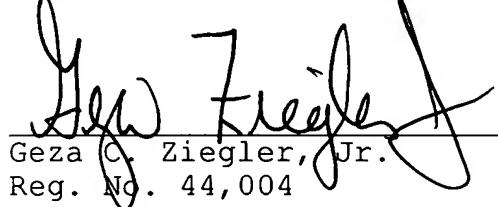
"Amberlyst-15 (H<sup>+</sup>) -NaBH<sub>4</sub>-LiG1: An Effective Reduct for Oximes and Hydrazones", Bipul Baruah et al.

Copies of these references are enclosed together with a Form PTO-1449.

The filing of this Statement is not to be construed as a representation that a search has been made regarding the claimed invention (37 C.F.R. §1.97(g)) or that no other possible material information exists. In addition, the filing of this Information Disclosure Statement is not to be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

The Commissioner is hereby authorized to charge payment for any fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,

  
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Geza C. Ziegler, Jr.  
Reg. No. 44,004

28 October 2004  
Date

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Page No.: 1 of 8

<b>INFORMATION DISCLOSURE CITATION FORM FOR PATENT APPLICATION (FORM PTO-1449)</b> (Substitute)		Docket No.: 785-011731-US (PAR)		Serial No.: 10/804,558		
		Applicant(s): CUBERES ALTISEN, et al.				
		Filing Date: 3/19/04	Group:			
<b>U.S. PATENTS</b>						
Initials	Patent Number	Issue Date	Name	Class	Sub-class	Filing date
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	DE 299 21 689 U1	5/23/01	Germany	Thomas Emde		no
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"Novel Syntheses of 1,3,3-Trinitroazetidine", Alan R. Katritzky, et al., J. Heterocyclic Chem. 31, 271-275 (1994)						
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"Synthesis of Novel Four-Membered Ring Amino Acids as Modulators of the <i>N</i> -Methyl-D-Aspartate (NMDA) Receptor Complex", Alan P. Kozikowski, et al., Synlett, 1991, (11), 783-784						
"Synthesis of 1,3,3-Trinitroazetidine", Theodore Axenron, et al., Tetrahedron Letters, Vol. 34, No. 42, pp. 6677-6680, 1993						
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Initial if reference was considered, whether or not citation is in conformance with MPEP. Mark through citation if not considered. Include a copy of this citation form with your next correspondence to the Applicant(s).						

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	“Studies of $\beta$ -Methyl-1-and 3-Phenyl Allyl Chlorides”, M.Y. Shandala, et al., Tetrahedron Vol. 40, No. 7, pp. 1195 to 1198, 1984					
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	“Activation de la liaison silicium-halogene par les halogenures de bismuth (III). Halogenation des alcohols: perspectives et mecanisme [1]”, Mireille Labrouillere, et al., Bull Soc Chim Fr (1995) 132, 522-530					
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	“A Short Enantioselective Synthesis of N-Boc- $\alpha$ -Amino Acids from Epoxy Alcohols”, Marta Poch, et al., Tetrahedron Letters, Vol. 34, No. 48, pp. 7781-7784, 1993					
	“A Versatile Enantiospecific Approach to 3-Azetidinols and Aziridines”, Marta Poch, et al., Tetrahedron Letters, Vol. 32, No. 47, pp. 6935-6938, 1991					
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		Applicant(s): CUBERES ALTISEN, et al.				
		Filing Date: 3/19/04	Group:			
<b>U.S. PATENTS</b>						
Initials	Patent Number	Issue Date	Name	Class	Sub-class	Filing date
<b>U.S. PATENT PUBLICATIONS</b>						
Initials	Publication No.	Pub. Date	Name	Class	Sub-class	Filing Date
<b>FOREIGN PATENT DOCUMENTS</b>						
Initials	Document Number	Date	Country	Name		Translation? Yes/No/n/a
<b>OTHER DOCUMENTS (Title, Author, Date, Pages, Etc., if known)</b>						
	"Carrage Induced Edema in Hind Paw of the Rat as an Assay for Antiinflammatory Drugs", Charles A. Winter, et al., Proc. Soc. Exp. Biol. Med. 111, 544-547 (1962)					
	"Selective Inhibition of Cyclooxygenase (COX)-2 Reverses Inflammation and Expression of COX-2 and Interleukin 6 in Rat Adjuvant Arthritis", Gary D. Anderson, et al., J. Clin. Invents, Volume 97, Number 11, June 1996, 2672-2679					
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	"New Cyclooxygenase-2/5-Lipoxygenase Inhibitors. 1. 7- <i>tert</i> -Butyl-2,3-dihydro-3,3-dimethylbenzofuran Derivatives as Gastrointestinal Safe Antiinflammatory and Analgesic Agents: Discovery and Variation of the 5-Keto Substituent", John M. Janusz, et al., J. Med. Chem, 1998, 41, 1112-1123					
	4 pages of Product Information by Product Number from <a href="http://www.caymanchem.com">www.caymanchem.com</a> product catalog					
	"Amberlyst-15(H <sup>+</sup> )-NaBH <sub>4</sub> -LiGI: An Effective Reducto for Oximes and Hydrazones", Bipul Baruah et al., Synlett 1999, No. 4, 409-410					
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